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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,331	01/18/2000	John J. Harrington	5817-7L	9576
959	7590	10/05/2004	EXAMINER	
LAHIVE & COCKFIELD, LLP. 28 STATE STREET BOSTON, MA 02109			SHUKLA, RAM R	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/484,331

Applicant(s)

HARRINGTON ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 69 and 70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. The response filed 6/23/04 and the supplemental response filed 7/21/04 have been received and entered.
2. Claims 62 and 68 have been canceled.
3. Claims 69 and 70 are pending and under consideration.
4. It is noted that no new rejections have been set forth in this office action and the rejections set forth in this office action are the only rejections pending in the instant application. Any rejection not repeated in this office action has been withdrawn.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 69 and 70 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record set forth in the previous office action of 12/23/03.

### ***Response to Arguments***

Applicant's arguments filed 6/23/04 have been fully considered but they are not persuasive.

Applicants argue:

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On page 3 of the Office Action the Examiner states that the only references to the term "drug discovery" are found on page 7, lines 28-30 and page 11, lines 27-29 continued through page 12, lines 1 and 2. Applicants point out that the specification refers to drug discovery in more areas. In addition to the text cited by the Examiner, reference to use of the invention for drug discovery is also found on page 32, lines 1-6, page 35, lines 26-30 and page 69, lines 14-18. Applicants have also referenced the disclosure in Applicants' earliest priority application 09/941,223 in page 5, last paragraph, page 9, fourth paragraph, page 12, last paragraph, page 16, second paragraph and page 45, third paragraph.

First, there is no such priority application as 09/941,223. If the applicants mean to 08/941,223, all the pages cited by the applicants have been reviewed and the descriptions in the priority application are the same as those in the instant application. In other words, the priority document does not add anything new to the description of the instant application. To clarify the point further, following is a comparison of different parts of the instant application with that of the 08/941,223:

Instant application	08/941,223
Page 7	page 5
Page 12	page 9
Page 32	page 12
Page 35	page 16
Page 69	page 45

The corresponding pages of the instant application and the priority application contain either exactly same statements or slight variations and none of these cited parts of the instant application or of the priority application recite the claimed invention (see pages 2 and 3 of the previous office action). Therefore, the cited parts do not describe the claimed invention.

Next applicants argue that there is adequate written description for the claim as a whole and in support of their argument they cite a declaration by Dale Dhanoa. Applicants refer to the interview with Examiner Shukla and SPE Reynolds and describe the position taken by the examiners:

In the interview, Examiner Shukla and Supervisory Examiner Reynolds took the position that the specification does not describe the claim as a whole, i.e., the combination of steps (a)-(c) with steps (d)-(e). The Examiners took the position that ANY disclosure of using the RAGE technology for compound testing would, at best, be limited to testing a compound against a purified protein, not a cell.

However, characterizing examiner's position that specification does not describe combination of steps a-c with d-e and that there was a support for testing a compound against a purified protein not a cell, is incorrect because the examiner's position is described in the previous office action and reiterated in the instant office action. There is no other position.

With respect to the declaration, it is noted that while the declaration was considered previously when it was presented, it has been reconsidered and the declaration is not persuasive to obviate the rejection as discussed below. It is emphasized that the declaration was previously submitted in response to a written description requirement rejection for description of compounds in the office action of 1/13/03 and the rejection was withdrawn after the consideration of the declaration (see the advisory action of 8/5/03). First, it is noted that the declaration lists 09/941,223 as a US Patent application, which is incorrect and the same mistake is present in applicants' response. Therefore, it is not clear which patent application did Dr. Dhanoa see. Furthermore, from the declaration it is also unclear whether Dr. Dhanoa saw the claims and the rejection first before seeing the specification because this would result in Dr. Dhanoa analyzing the specification keeping in mind the claim language. While the declaration discusses the state of the art of drug discovery at the time of the invention, the declaration does not

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address the issue: how could the specification lead an artisan to the specific steps recited in the claim? In other words, how would an artisan know what specific steps were contemplated by the applicants at the time of the invention. And the declaration cannot address this issue.

Therefore, the new matter rejection of claims 69 and 70 is maintained for reasons of record.

7. Claim 69 and 70 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record set forth in the previous office action of 12/23/03. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

### ***Response to Arguments***

Applicant's arguments filed 6/23/04 have been fully considered but they are not persuasive.

In view of the cancellation of claim 62, the issue of integration of the vector by homologous recombination in step (a) is moot. Next, applicants argue the issue of desired gene and desired phenotype in step (e) and have submitted a diagrammatic representation of how the two mechanisms would work. However, these schemes do not address the fundamental issue raised in the previous office action:

(i) the specification does not teach any method of drug discovery, either using cells or protein product purified from cells. The only references to a term "drug discovery" are on pages 7 and 11, however, these sections of the specification do not teach how to practice the claimed drug discovery methods.

(ii) it would not have been routine to determine the ability of one or more compounds to interact with the product of the activated gene since such would have depended on the characteristics/properties of the gene or gene product and

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the compound. This in turn would require characterization of the gene or gene product and a compound, which could interact with the gene product.

Applicants arguments that an artisan could take any compound (as discussed in the declaration by Bennani) are not persuasive because an artisan would need to know the structure of the compound, structure of the gene product and requirements for the interaction of the compound to interact with a gene product to practice step (e). Applicants did not discuss where the specification discusses how to determine the ability of one or more compounds to interact with a product of an activated gene, what characteristics of a gene product or compound will be used in determining such.

While applicants provide elaborate schemes and explanations, none of these are present in the specification and therefore an artisan would not have had these descriptions for practicing the claimed invention. Regarding the issue of phenotype, applicants argue that it is irrelevant whether the change in phenotype is due to one or multiple genes. However these arguments are not persuasive because the issue is relevant since the method is for finding a drug for a certain gene. Applicants using of drug resistance phenotype is misplaced because the method is for screening of compounds that affect gene product of a gene and not for screening of compounds that affect drug resistance.

Therefore, the specification, except for a mere germ idea of drug discovery, does not teach how to practice a method of drug discovery and the enablement rejection set forth in the previous office action of 12/23/03 is maintained.

No claim is allowed.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory


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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735 . The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (571) 272-0532.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632



**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**